

### REMARKS

The Office Action dated December 22, 2000, has been reviewed in detail along with all references made of record. Reconsideration of the claims of the instant application is respectfully requested in view of the following remarks.

Applicants would like to extend its appreciation to the Examiner for the time and attention accorded this case. As will be set forth in detail herebelow, the issues raised by the Office in the outstanding Office Action, when reconsidered in light of the foregoing amendments and the following comments, should be resolved in Applicants' favor.

#### Allowable Subject Matter

Applicants acknowledge, with appreciation, the indicated allowability of Claims 8, 11 and 19, if rewritten in independent form. As discussed below, new independent claims 24, 28 and 73 correspond, respectively, to allowable claims 8, 11 and 19, rewritten in independent form to include the limitations of the base claim and any intervening claims.

#### Examiner Interview

Applicants are most grateful for the courtesies extended by the Examiner and the Supervisory Primary Examiner to Applicants' representatives in connection with a personal Interview held at the U.S. Patent and Trademark Office on March 16, 2001. As warranted, various aspects of the Interview are referred to herebelow.

Information Disclosure Statement Filed on December 15, 2000

The Form PTO-1449 accompanying the Information Disclosure Statement filed on December 15, 2000, has not been initialed and returned to the under-signed. Applicants request the Examiner to initial the noted Form PTO-1449 to indicate his consideration of the item(s) listed thereon, and to return an initialed copy of the Form PTO-1440 with the next Patent Office correspondence.

Newly Filed Information Disclosure Statement

On May 17, 2001, Applicants submitted an additional Information Disclosure Statement, along with the requisite submission fee. Applicants request the Examiner to consider the submitted information and to initial the accompanying Forms PTO-1449.

Prior Art Rejection

Claims 4-7, 9, 10, 12-18 and 20-23 stand rejected under 35 U.S.C. 102 in view of U. S. Patent No. 5,742,403 to Cornacchia et al.

By this Amendment, Claims 4-23 have been cancelled while Claims 24-103 have been newly presented. In view of the remarks presented herebelow, it is respectfully submitted that the newly presented claims fully distinguish over the applied art.

As best understood, Cornacchia relates to a device which provides for the automatic injection of radionuclide solution. Two syringes are present, one for injecting a quantity of radionuclide solution and the other for injecting a saline solution which flushes the

tubing through which radionuclide solution is delivered. Injection takes place upon receipt of either an automatic or manual prompt. As a hedge against false alarms, delay cycle is implemented to permit verification of the prompt. As described in col. 2, lines 20-26 of Cornacchia, flushing apparently takes place only after a course of injecting radionuclide solution. There is apparently no provision for carrying out any conceivable protocol other than a two-phase protocol of radionuclide injection followed by saline solution, or flushing medium, injection.

Though the cancellation of Claims 4-23 effectively renders the present rejection moot, the following remarks are provided to support Applicants' contention that newly presented Claims 24-103 fully distinguish over the applied art.

Independent Claim 24 corresponds to previously pending Claim 8 rewritten in independent form. Accordingly, since previously pending Claim 8 has already been indicated by the Office as being allowable, it is respectfully submitted that Claim 24 is allowable as presented. It was confirmed during the Examiner Interview that no further modifications to the recitations now present in Claim 24 would be required for allowability.

Claims 25-27 depend from Claim 24 and recite various refining features. By virtue of dependence from what is apparently an allowable claim, it is respectfully submitted that Claims 25-27 are allowable as presented.

Independent Claim 28 corresponds to previously pending Claim 11 rewritten in independent form. Accordingly, since previously pending Claim 11 has already been indicated by the Office as being allowable, it is respectfully submitted that Claim 28 is allowable as presented. It was confirmed during the Examiner Interview that no further modifications to the recitations now present in Claim 28 would be required for allowability. It should be noted that

the term "pre-programmed" has been left out in an effort to more accurately recite the nature of the feature at hand.

Claims 29-31 depend from Claim 28 and recite various refining features. By virtue of dependence from what is apparently an allowable claim, it is respectfully submitted that Claims 29-31 are allowable as presented.

Claims 71 and 72 are method claims which recite similar subject matter as Claims 24 and 28, respectively. For similar reasons as discussed above in connection with Claims 24 and 28, it is respectfully submitted that Claims 71 and 72 are allowable as presented.

Independent apparatus Claim 32 relates to an apparatus in which the following are provided: "means for programming a first phase of an injection procedure"; "means for programming a second phase of an injection procedure, subsequent to a first phase of an injection procedure" and "means for programming a third phase of an injection procedure, subsequent to a second phase of an injection procedure, as a phase other than a flushing medium phase". It is respectfully submitted that such features fully distinguish over the teachings of Cornacchia.

First, it is to be recalled that, in the course of the Examiner Interview, the use of "means plus function" language was recommended by the Examiners as a measure for increasing the likelihood of allowability. Accordingly, this recommendation has presently been carried out in connection with Claim 32 and several other independent claims.

As such, the result would appear to be the accordance of functional significance to particular structures within the apparatus contemplated by Claim 32. Such structures, in turn, are now recited as performing specific, dedicated functions. To the extent that such functions are collectively absent or unattainable in any prior art, it is respectfully submitted that Claim 32 fully distinguishes over such prior art.

Accordingly, it is respectfully submitted that the teachings of Cornacchia fall far short of the structures and associated functions contemplated in connection with Claim 32. Particularly, Cornacchia appears to contemplate only one conceivable protocol, namely, that of injecting radionuclide solution followed by an injection of saline, or flush, solution. Claim 32, on the other hand, recites that, through available structure, not only are three phases of an injection procedure available, but a third phase is programmable as a phase other than a flushing medium phase. A non-restrictive example of the structure which may carry out such a function may be found, for example, in Figure 4 of the instant application, where a third row of entry fields 214/216 are used in programming a contrast medium phase as a third phase of an injection procedure. In one embodiment of the present invention, upon the automatic appearance of the aforementioned third row of entry fields 214/216 subsequent to the operator's programming of the first two phases of the procedure, the operator may press touch field "3" in column 218, or for that matter any conceivable icon, pop-up button or other analogously performing item, to direct that the third phase will be a contrast medium phase. Subsequently, as discussed in the paragraph bridging pages 9 and 10 of the instant specification, the entry of actual data could be accomplished by touching on each entry field in the third row of entry fields 214 and 216 and, in each instance, entering data by way of a keypad which may appear on the screen. Together, touch field "3" in column 218, the third row of entry fields 214/216, and the aforementioned keypad may, in accordance with an exemplary embodiment of the present invention, constitute the available structure for programming a third phase of an injection procedure as a phase other than a flushing medium phase.

It is clear that analogous structure, available to perform the specific function of programming a third phase of an injection procedure as a phase other than a flushing medium phase, is neither taught nor suggested by Cornacchia. For one, Cornacchia does not even contemplate the possibility of a third phase. Additionally, available structure for performing the

tasks contemplated by Claim 32 is lacking. Furthermore, even if it were to be argued that the Cornacchia reference could somehow be construed as disclosing structure that could in some manner be manipulated in an effort to perform the functions contemplated by Claim 32, it is respectfully submitted that Claim 32 would still distinguish over Cornacchia. Particularly, there is nothing in the Cornacchia reference to suggest that the device disclosed therein could or should be reconfigured to carry out a protocol involving a third phase as a phase other than flushing; the motivation to do so is simply not apparent from a reading of the reference. Particularly, such versatility is not apparent from the teachings of Cornacchia, and any attempt to reconfigure the Cornacchia device to achieve such versatility would require such a dramatic change in structure as to effectively disable the Cornacchia device from carrying out its originally intended purpose (that is, of providing radionuclide medium followed by flushing medium). Thus, to arrive at the present invention (as defined by Claim 32) as a supposedly "obvious" extension of the teachings of Cornacchia would require tremendous hindsight, with only the present invention itself available as a guide. Accordingly, it is respectfully submitted that the Cornacchia reference cannot possibly be construed as teaching or suggesting the subject matter recited by Claim 32.

In view of the foregoing, it is respectfully submitted that Claim 32 fully distinguishes over the applied art.

Claims 33-38, properly dependent from Claim 32, recite additional features which are believed to distinguish even more fully over the applied art. For instance, Claim 33 recites that structure is available for programming a first phase of an injection procedure as a phase other than a contrast medium phase. There is nothing in Cornacchia to teach or suggest that the device disclosed therein could or should be capable of performing such a task. Claim 34, on the other hand, essentially indicates that structure is available for programming a first phase of an injection procedure as a contrast medium phase. Though it could arguably be noted that

Cornacchia contemplates a "first phase" of an "injection procedure" as a "contrast medium phase", it will be noted that Claim 34 depends from Claim 33. Thus, whereas the present invention, as defined by Claim 34, contemplates structure both for programming a first phase as a phase other than a contrast medium phase and for programming a first phase as a contrast medium phase, the Cornacchia device clearly does not afford such versatility. More particularly, such versatility is not apparent from the teachings of Cornacchia, and any attempt to reconfigure the Cornacchia device to achieve such versatility would require such a dramatic change in structure as to effectively disable the Cornacchia device from carrying out its originally intended purpose (that is, of providing radionuclide medium followed by flushing medium).

Claim 35, as presented, contemplates the provision of structure both to program a second phase as a contrast medium phase and to program a contrast medium phase as a flushing medium phase. Again, such versatility is not apparent from the teachings of Cornacchia, and any attempt to reconfigure the Cornacchia device to achieve such versatility would require such a dramatic change in structure as to effectively disable the Cornacchia device from carrying out its originally intended purpose (that is, of providing radionuclide medium followed by flushing medium).

Claim 36, as presented, contemplates the provision of structure to program a third phase as a flushing medium phase. Since Cornacchia et al. does not even contemplate the provision of a third phase, it is respectfully submitted that it cannot possibly be construed as teaching or suggesting the subject matter of Claim 36.

Claims 37 and 38 relate, respectively, to the provision of a hold phase and a pause phase. A more detailed discussion of such features is provided herebelow with relation to Claims 62 and 63.

In view of the foregoing, and by virtue of dependence from Claim 32, it is respectfully submitted that Claims 33-38 fully distinguish over the applied art.

Claims 74-81 are method claims which, essentially, correspond to the subject matter presented by Claims 32-38 (essentially, the correspondence between the two sets of Claims is one-to-one, except that Claim 35 corresponds to both Claims 77 and 78, which "split" the subject matter of Claim 35 into two). Accordingly, the remarks presented above in connection with Claims 32-38 are relevant here. It is also to be noted that, in the course of the Examiner Interview, the use of "step plus function" language in method claims was recommended by the Examiners as a measure for increasing the likelihood of allowability. Accordingly, this recommendation has presently been carried out in connection with Claim 70 and several other independent claims.

A primary difference, of course, between method Claims 74-81 and apparatus Claims 32-38 is that the former recite functional steps while the latter recite particular structures for carrying out various functions. However, it is respectfully submitted that the remarks presented above in connection with Claims 32-38 are still relevant here, in that it is apparent that the Cornacchia reference still cannot be construed as teaching or suggesting the performance of various tasks that are contemplated by method Claims 74-81. Again, the type of versatility contemplated by Claims 74-81 is not apparent from the teachings of Cornacchia, and any attempt to reconfigure the Cornacchia device to achieve such versatility would require such a dramatic change in structure as to effectively disable the Cornacchia device from carrying out its originally intended purpose (that is, of providing radionuclide medium followed by flushing medium).

In view of the foregoing, it is respectfully submitted that Claims 74-81 fully distinguish over the applied art.



Independent apparatus Claim 39 relates to an apparatus in which the following are provided: "means for programming a first phase of an injection procedure"; "means for programming a second phase of an injection procedure, subsequent to a first phase of an injection procedure"; "means for programming a third phase of an injection procedure, subsequent to a second phase of an injection procedure" and "means for programming a fourth phase of an injection procedure, subsequent to a third phase of an injection procedure, as a phase other than a flushing medium phase". It is respectfully submitted that such features fully distinguish over the teachings of Cornacchia.

Again, the use of "means plus function" language, as recommended by the Examiners at the Examiner Interview, would appear to accord functional significance to particular structures within the apparatus contemplated by Claim 39. Such structures, in turn, are now recited as performing specific, dedicated functions. To the extent that such functions are collectively absent or unattainable in any prior art, it is respectfully submitted that Claim 39 fully distinguishes over such prior art.

Accordingly, it is respectfully submitted that the teachings of Cornacchia fall far short of the structures and associated functions contemplated in connection with Claim 39. In this connection, the remarks presented above in connection with Claim 32 are at least as relevant here, since Claim 39 contemplates the provision of four phases in a protocol whereas Cornacchia appears to contemplate only the single protocol of injecting radionuclide solution followed by an injection of saline, or flush, solution. More particularly, Claim 39 recites that, through available structure, not only are four phases of an injection procedure available, but a fourth phase is programmable as a phase other than a flushing medium phase. A non-restrictive example of the structure which may carry out such a function may be found, for example, in Figure 5 of the instant application, where a fourth row of entry fields 214/216 are used in programming a contrast medium phase as a fourth phase of an injection procedure. In one embodiment of the

present invention, upon the automatic appearance of the aforementioned fourth row of entry fields 214/216 subsequent to the operator's programming of the first three phases of the procedure, the operator may press touch field "4" in column 218, or for that matter any conceivable icon, pop-up button or other analogously performing item, to direct that the fourth phase will be a contrast medium phase. Subsequently, as discussed in the paragraph bridging pages 9 and 10 of the instant specification, the entry of actual data could be accomplished by touching on each entry field in the third row of entry fields 214 and 216 and, in each instance, entering data by way of a keypad which may appear on the screen. Together, touch field "3" in column 218, the fourth row of entry fields 214/216, and the aforementioned keypad may, in accordance with an exemplary embodiment of the present invention, constitute the available structure for programming a fourth phase of an injection procedure as a phase other than a flushing medium phase.

For similar reasons as discussed above in connection with Claim 32, it is clear that analogous structure, available to perform the specific function of programming a fourth phase of an injection procedure as a phase other than a flushing medium phase, is neither taught nor suggested by Cornacchia. Accordingly, it is respectfully submitted that the Cornacchia reference cannot possibly be construed as teaching or suggesting the subject matter recited by Claim 39.

In view of the foregoing, it is respectfully submitted that Claim 39 fully distinguishes over the applied art.

Claims 40-46, similarly to Claims 33-38, recite additional features which are believed to distinguish even more fully over the applied art. Thus, similar to the reasons discussed above in connection with Claims 33-38, and by virtue of dependence from Claim 39, it is respectfully submitted that Claims 40-46 fully distinguish over the applied art.

Claims 83-91 are method claims which, essentially, correspond to the subject matter presented by Claims 40-46 (essentially, the correspondence between the two sets of Claims is one-to-one, except that Claim 42 corresponds to both Claims 85 and 86, which "split" the subject matter of Claim 42 into two, and Claim 43 corresponds to both Claims 87 and 88, which "split" the subject matter of Claim 43 into two). Accordingly, the remarks presented above in connection with Claims 40-46 are relevant here. The remarks presented above in connection with Claims 74-81 are also relevant here, especially as regards the differences between method claims and apparatus claims.

In view of the foregoing, it is respectfully submitted that Claims 83-91 fully distinguish over the applied art.

Independent apparatus Claim 47 recites that a control device comprises "means for programming a first phase of an injection procedure as a phase other than a contrast medium phase". It is respectfully submitted that Cornacchia does not teach or suggest such a feature. Particularly, as discussed heretofore, Cornacchia appears only to contemplate a single protocol that involves the injection of a radionuclide followed by the injection of saline solution. Furthermore, and for reasons similar to those discussed above in connection with Claims 32 and 39, it is respectfully submitted that the function associated with the structure recited in Claim 47 is not an obvious extension of the teachings of Cornacchia, in that the Cornacchia device would have to be reconfigured beyond recognition in order to carry out such a function. Accordingly, it is respectfully submitted that Claim 47 fully distinguishes over the applied art.

Claims 48-65, properly dependent from Claim 47, recite additional features and refinements that are believed, in combination with Claim 47, to distinguish even more fully over the applied art. Significant among these are Claims 59 and 61 which, respectively, recite the

provision of a hold phase and a pause phase. A more detailed discussion of such features is provided herebelow with relation to Claims 66 and 67.

By virtue of dependence from Claim 47, it is respectfully submitted that Claims 48-65 fully distinguish over the applied art.

Independent Claim 92 is a method claim which, essentially, corresponds to the subject matter presented by Claim 48. Accordingly, the remarks presented above in connection with Claim 48 are relevant here. The remarks presented above in connection with Claims 74-81 are also relevant here, especially as regards the differences between method claims and apparatus claims.

Claims 93-101, properly dependent from Claim 92, recite additional features and refinements that are believed, in combination with Claim 92, to distinguish even more fully over the applied art. Significant among these are Claims 95 and 97 which, respectively, recite the provision of a hold phase and a pause phase. A more detailed discussion of such features is provided herebelow with relation to Claims 66 and 67.

In view of the foregoing, it is respectfully submitted that Claims 93-101 fully distinguish over the applied art.

Independent apparatus Claim 66 recites, *inter alia*, that a control device comprises "means for programming a second phase of an injection procedure, subsequent to a first phase of an injection procedure, as a hold phase". It is respectfully submitted that Cornacchia does not teach or suggest such a feature. Particularly, Cornacchia appears only to contemplate a delay that takes place before, essentially, any phase of any injection procedure is carried out. As discussed previously, such a delay only takes place before radionuclide is administered. There appears to be no teaching or suggestion in Cornacchia that any type of delay or hold could or should take

place subsequent to the administration of radionuclide. Indeed, as stated in col. 2, lines 20-23 of Cornacchia, "[after] the correct amount of the radionuclide has been injected, the computer initiates a flush sequence which causes the saline solution within the second syringe to be injected through the intravenous tubing." Here, and elsewhere in the Cornacchia disclosure, there is nothing to teach or suggest any controllable hold or delay after radionuclide injection.

Furthermore, other features recited by Claim 66 are simply lacking from the Cornacchia disclosure, including arrangements for programming a first phase as a contrast medium or flushing medium phase. As discussed heretofore, Cornacchia only appears to contemplate a first phase as a "contrast medium" phase. Thus, the function of programming of a first phase as a "flushing medium" phase would not represent an obvious extension of the teachings of Cornacchia, in that the Cornacchia device would have to be reconfigured beyond recognition in order to carry out such a function.

In view of the foregoing, it is respectfully submitted that Claim 66 fully distinguishes over the applied art.

Independent apparatus Claim 67 recites, *inter alia*, that a control device comprises "means for programming a pause phase to occur between first and second phases of an injection procedure". It is respectfully submitted that Cornacchia does not teach or suggest such a feature. Again, Cornacchia appears only to contemplate a delay that takes place before, essentially, any phase of any injection procedure is carried out. There appears to be no teaching or suggestion in Cornacchia that any type of delay or pause could or should take place subsequent to the administration of radionuclide and prior to the administration of saline medium. The passage of Cornacchia cited above in connection with Claim 66 is thus also relevant here. Particularly, there is nothing, in that passage or elsewhere in Cornacchia, to teach or suggest any controllable

delay or pause between radionuclide injection and saline injection; indeed, the transition from one to the other appears uncontrollable and automatic.

As with Claim 66, other features recited by Claim 67 are lacking from the Cornacchia disclosure, including arrangements for programming a first phase as a contrast medium or flushing medium phase, and also arrangements for programming a second phase as a contrast medium or flushing medium phase. Again, Cornacchia only appears to contemplate a first phase as a "contrast medium" phase. Thus, the function of programming of a first phase as a "flushing medium" phase or a second phase as a "contrast medium" phase would not represent obvious extensions of the teachings of Cornacchia, in that the Cornacchia device would have to be reconfigured beyond recognition in order to carry out such functions.

In view of the foregoing, it is respectfully submitted that Claim 67 fully distinguishes over the applied art.

Independent Claims 102 and 103 are method claims which, essentially, correspond to the subject matter presented by Claims 66 and 67, respectively. Accordingly, the remarks presented above in connection with Claims 66 and 67 are relevant here. The remarks presented above in connection with Claims 74-81 are also relevant here, especially as regards the differences between method claims and apparatus claims.

In view of the foregoing, it is respectfully submitted that Claims 102 and 103 fully distinguish over the applied art.

Independent apparatus Claims 68, 69 and 70 are each essentially similar to Claim 47, with the exceptions that: in Claim 68, the term "programming" is replaced by the term "establishing"; in Claim 69, the term "means" is replaced by the term "arrangement"; and Claim 70 incorporates both of the changes just mentioned. In each case, the subject matter remains

essentially the same as in Claim 47 while slightly different terminology is provided. It is respectfully submitted that such changes in terminology do not in any way undermine the distinguishability of the associated subject matter over the applied art. Accordingly, the remarks presented above in connection with Claim 47 are also relevant to Claims 68, 69 and 70. Thus, it is respectfully submitted that Claims 68-70 fully distinguish over the applied art.

Independent apparatus Claim 73 corresponds to previously pending Claim 19 rewritten in independent form. Accordingly, since previously pending Claim 19 has already been indicated by the Office as being allowable, it is respectfully submitted that Claim 73 is allowable as presented. It was confirmed during the Examiner Interview that no further modifications to the recitations now present in Claim 73 would be required for allowability.

In view of the foregoing, it is respectfully submitted that Claims 24-103 are allowable as presented.

#### References Made of Record but not Applied

The references made of record and considered by the Office to be "pertinent to applicant's disclosure" have been reviewed. Applicants acknowledge that the Office has deemed such references not sufficiently relevant to have been relied upon in the outstanding Office Action. However, to the extent that the Office may apply such references against the claims in the future, Applicants are prepared to fully respond thereto.

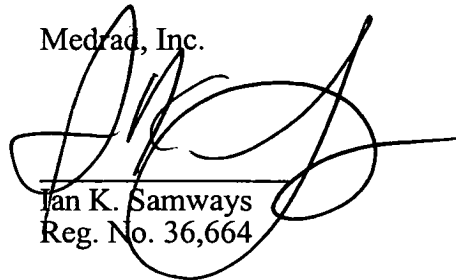
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In summary, Applicants respectfully submit that Claims 24-103 are presently in condition for allowance. Notice to the effect is hereby earnestly solicited.

Respectfully submitted,

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